BENZALKONIUM CHLORIDE- benzalkonium chloride 0.13% soap
Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Germ-X Antibacterial Hand Soap 858.000/858AA

Active ingredient

Benzalkonium chloride 0.13%

Purpose

Antibacterial

Use

for handwashing to decrease bacteria on the skin

Warnings

For external use only: hand only

When using this product

- avoid contact with eyes. If contact occurs, rinse eyes thoroughly with water

Stop use and ask a doctor if

- irritation or redness develops
- condition persists for more than 72 hours

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- wet hands
- apply palmful to hands
- scrub thoroughly
- rinse thoroughly

Inactive ingredients

water, lauramine oxide, cocamidopropyl betaine, lauramidopropylamine oxide, sodium chloride, myristamidopropylamine oxide, glycerin, fragrance, limonene, distearet-75 IPDI, PEG-150 distearate, citric acid, tetrasodium EDTA, benzophenone-4, sodium benzoate, orange 4, red 33

*Washing hands helps wash away bacteria and germs

Distributed by:

Vi-Jon, LLC, St. Louis, MO 63114

principal display panel

germ-X

SINCE 1997

ANTIBACTERIAL

HAND SOAP

CITRUS PEEL SCENT

WASHES AWAY GERMS*

pH Balanced, Dermatologist Tested

FORMULA MADE IN USA EMPLOYEE-OWNED

16 FL OZ (473 mL)

BENZALKONIUM CHLORIDE

benzalkonium chloride 0.13% soap

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11344-858
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 g in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
LAURAMINE OXIDE (UNII: 4F6FC4MI8W)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
LAURAMIDOPROPYLAMINE OXIDE (UNII: I6KX160QTV)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
MYRISTAMIDOPROPYLAMINE OXIDE (UNII: 3HSF539C9T)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIMONENE, (+)- (UNII: GFD7C86Q1W)	
DISTEARETH-75 ISOPHORONE DIISOCYANATE (UNII: 5365FJ30SC)	
PEG-150 DISTEARATE (UNII: 6F36Q0I0AC)	
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	
EDETATE SODIUM (UNII: MP1J8420LU)	
SULISOBENZONE (UNII: 1W6L629B4K)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
D&C ORANGE NO. 4 (UNII: Q1LIY3BO0U)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11344-858-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2021	
2	NDC:11344-858-32	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	04/13/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/10/2017	

Labeler - Vi-Jon, LLC (150931459)

Registrant - Vi-Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(11344-858)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(11344-858)

Establishment

Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		150931459	manufacture(11344-858)

Revised: 5/2021